REMARKS

Applicants appreciate the thorough and detailed examination of the present application as evidenced by the Office Action dated January 12, 2006 (hereinafter, the "Office Action"). The concerns raised by the Examiner are addressed below as set forth in the Office Action.

I. Specification

Applicants submit a new title that is further indicative of the subject matter to which the claims are directed, as suggested by the Examiner.

II. Information Disclosure Statement

The Office Action states that "[t]he information disclosure statement filed 20 July 2004[1] fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The foreign and non-patent literature references were not located in the instant file nor any parent file." Office Action, page 2.

The Manual of Patent Examining Procedure (M.P.E.P.) states the following:

> The examiner will consider information which has been considered by the Office in a parent application when examining (A) a continuation application filed under **37 CFR 1.53(b)** ** (B) a divisional application filed under **37 CFR 1.53(b)** ** or (C) a continuation-in-part application filed under **37 CFR 1.53(b)**. A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.

M.P.E.P. §609.02(A)(2).

Applicants note that the information disclosure statement (IDS) submitted by Applicants included a copy of a form PTO-1449 as filed in parent U.S. Patent Application Serial No. 10/434,259 with the Attorney Docket Number of the parent application struck through and the Attorney Docket number of the present application written thereon. Applicants further note that the references cited in the IDS filed in the present application

[1] Applicants submitted the information disclosure statement on January 30, 2004 at the time of filing the present application.

appear on the face of the issued patent for the parent application, U.S. Patent No. 6,667,321. *See* attached pages 1-3 of the '321 patent. Accordingly, it is Applicants' belief that the USPTO has previously received and/or reviewed the references cited in the IDS, and Applicants are now entitled to have the references considered, and in the event of allowance, listed on a patent issuing from the present application. Applicants are willing to resubmit the references; however, in contrast to the statements set forth in the Office Action, Applicants believe that the date of submission should be considered the original date of submission and not the date of re-submission.

The Office Action further states that "the listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98 and 37 CFR 1.98(a)(2) . . . Therefore, the references cited in the Search Report have not been considered." Office Action, page 3. In addition to citing the Search Report accompanying the Norwegian Office Action, Applicants also separately listed the references cited therein in the IDS. The Examiner has initialed and signed the form PTO-1449, which lists these references. Thus, it is Applicants' belief that the references cited in the Search Report have been considered.

Lastly, Applicants respectfully request the return of a copy of an initialed and signed form PTO-1449 submitted by the Applicants on December 21, 2004.

Should there be any unresolved issues regarding the information disclosure statements submitted by the Applicants as discussed above, Applicants respectfully request that the Examiner contact the Applicants' undersigned representative using the contact information provided herein. The Examiner's consideration of the aforementioned issue is greatly appreciated.

III. Claim Rejections Under 35 U.S.C. §112

Claims 65, 68, 70, 73, 75, 78 and 83 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. *See* Office Action, page 4. In particular, the Office Action states that "[t]he term 'about' in the phrases 'about 5mg to about 60mg' (claim 65) and 'about 10 mg' (claim 68), for example, are relative terms which render the claims indefinite. Since the term 'about' is not defined by the claims and the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." Office Action, page 4. Applicants respectfully

disagree. Applicants respectfully submit that the term "about" is not indefinite as recited in the present claims.

The term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. *See* M.P.E.P. §2173.05(b) (citing *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968)). Similarly, the Federal Circuit held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. *See* M.P.E.P. §2173.05(b) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). The Federal Circuit, however, held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

Claims 65, 68, 70, 73, 75 78 and 83 recite "about" and not "at least about." Moreover, adequate measuring apparatuses are available to those of ordinary skill in the art so that such artisans would understand what is presently claimed.

Accordingly, Applicants respectfully submit that Claims 65, 68, 70, 73, 75 78 and 83 are not indefinite for at least these reasons, and Applicants respectfully request that these claim rejections be withdrawn.

IV. Claims Rejections Under 35 U.S.C. § 102

Claims 65-84 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 95/32957 to Astra Aktiebolag (hereinafter, "Astra Aktiebolag"). *See* Office Action, page 5.

It is well accepted that "[a]nticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000) (*relying on Electro Med. Sys. S.A. v. Cooper Life Scis.*, 32 USPQ2d 1017, 1019 (Fed Cir. 1994). A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be

enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964).

Claim 65 recites as follows:

> A pharmaceutical formulation in unit dosage form comprising per dose unit an amount of active ingredient within the range from about 5 mg to about 60 mg of 6-methoxy-2-[[(S)-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, **in pure form**, or pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, wherein said formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet.

As noted in the specification, in pure form refers to 6-methoxy-2-[[(S)-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole "present in amounts generally below limits detectable by conventional technology." Present Application, page 18, lines 12-13.

Astra Aktiebolag does not recite a pharmaceutical formulation as recited in Claim 65. In particular, Astra Aktiebolag discusses ethyl carbonate derivatives (e.g. ethoxycarbonyloxymethyl derivatives) of omeprazole. *See* Astra Aktiebolag, page 4, lines 16-31, among other places. Thus, Astra Aktiebolag does not teach or suggest the claimed invention and further fails to adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the present invention.

V. Nonstatutory Double Patenting Rejection

Claims 65-84 stand rejected on the ground of nonstatutory double patenting over the following:

1. Claims 1-68 of U.S. Patent No. 6,369,087;
2. Claims 1-12 of U.S. Patent No. 6,262,085;
3. Claims 1-30 of U.S. Patent No. 6,667,321;
4. Claims 1-24 of U.S. Patent No. 6,444,689;
5. Claims 1-5 of U.S. Patent No. 6,667, 324; and
6. Claims 1-45 of U.S. Patent No. 6,653,329.

See Office Action, pages 5-9.

In an effort to advance prosecution of this application to allowance, Applicants intend to submit a terminal disclaimer upon indication that the pending claims are allowed. Applicants' offer to submit the terminal disclaimer should not be construed as an admission

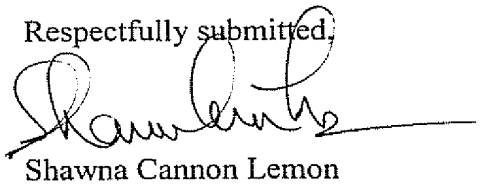
with respect to the nonstatutory double patenting rejections or the Examiner's characterization of Applicants' cited patents as set forth in the Office Action.

Claims 65-84 stand provisionally rejected on the ground of nonstatutory double patenting over Claims 1-101 of copending U.S. Patent Application Serial No. 10/855,809. Applicants respectfully submit that since the claims of the '809 application have not issued, Applicants do not believe that it is necessary to file a terminal disclaimer with this response. However, Applicants are prepared to provide a terminal disclaimer if it is determined to be necessary upon allowance of the relevant claims. Accordingly, Applicants respectfully request that the provisional rejection of Claims 65-84 be withdrawn.

Conclusion

At least in view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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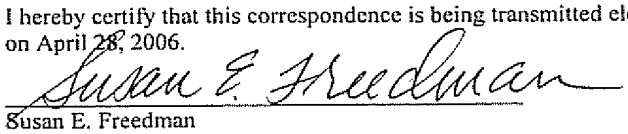

Susan E. Freedman
Date of Signature: April 28, 2006

US006667321B2

(12) **United States Patent**
Whittle et al.

(10) **Patent No.: US 6,667,321 B2**
(45) **Date of Patent: *Dec. 23, 2003**

(54) **ALKOXY SUBSTITUTED BENZIMIDAZOLE COMPOUNDS, PHARMACEUTICAL PREPARATIONS CONTAINING THE SAME, AND METHODS OF USING THE SAME**

(76) Inventors: **Robert R. Whittle**, 5006 Pine Needles Dr., Wilmington, NC (US) 28403; **Frederick D. Sancilio**, 2332 Ocean Point Dr., Wilmington, NC (US) 28405; **Grayson Walker Stowell**, 710 Darwin Dr., Wilmington, NC (US) 28405; **Douglas John Jenkins**, 6400 Purple Martin Ct., Wilmington, NC (US) 28411-8323; **Linda B. Whittall**, 2204 Splitbrook Ct., Wilmington, NC (US) 28411

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 19 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/189,659**

(22) Filed: **Jul. 3, 2002**

(65) **Prior Publication Data**

US 2003/0096845 A1 May 22, 2003

Related U.S. Application Data

(63) Continuation of application No. 10/057,659, filed on Jan. 25, 2002, now Pat. No. 6,444,689, which is a continuation of application No. 09/645,145, filed on Aug. 24, 2000, now Pat. No. 6,369,087, which is a continuation-in-part of application No. 09/519,976, filed on Mar. 7, 2000, now Pat. No. 6,262,085.

(60) Provisional application No. 60/150,878, filed on Aug. 26, 1999.

(51) **Int. Cl.**[7] **A61K 31/44**

(52) **U.S. Cl.** **514/338**

(58) **Field of Search** 514/338

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(57) **ABSTRACT**

Compounds represented by formula (Ia) are disclosed by the invention, along with compositions and complexes thereof, optionally in combination with compounds of formula (Ib). Pharmaceutical formulations and methods of making and using such compounds are also disclosed.

30 Claims, No Drawings

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